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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,184	12/28/2001	George Y. Daniloff	2232-162	6428
6449	7590	03/01/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/029,184

Applicant(s)

DANILOFF ET AL.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The amendment of 1/27/04 has been entered and claims 1-34 are currently pending in this application, claims 1-18 are considered here. Please update the specification regarding related cases.

In view of application 09/754,217 being abandoned, the double patenting rejection regarding that application is hereby withdrawn. And in view of the amendments to the claims, the rejections of record under 35 USC 101 and 112, second paragraph, are hereby withdrawn. Claim 18, if rewritten in independent form, would not be taught nor be fairly suggested by the references of record.

The amendment filed 1/27/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: A new chemical name has been introduced into the specification, (5,5-dimethyl-[1,3,2]dioxaborinan-2-yl) which is new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-13 of copending Application No. 10/113,063. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the present application, the independent claims do not include the specific compounds in the independent claims, only the dependent claims, whereas in '903 the specific compounds are recited in the independent claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by James.

James (5,503,770) entitled "Fluorescent Compound Suitable for Use in the Detection of Saccharides" teaches in column 1 lines 48+ and column 5 lines 12+,

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fluorescent compounds for the detection of monosaccharides including glucose in aqueous solutions. James specifically recites a compound in which the R is anthracene, hydrogen, dimethylamine, boronic acid, alkyl groups and Z is carbon in column 4, compounds 9 and 10. James further discloses that the compounds may be attached to a supporting material in column 3 lines 37-47. Two boronic acid groups bind to the hydroxy groups of glucose in column 5 lines 21-24. James teaches that the compound contains a fluorophore that is quenched by an unshared electron pair on the nitrogen atom in column 2 lines 59-63. The compounds may be utilized to detect glucose inside the body by utilizing an optical fiber in column 5 lines 54-63.

All the features of the claims are taught by James for the same function as claimed.

Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Bell.

Bell (6,366,793) filed 9/10/99 entitled "Minimally Invasive Methods for Measuring Analytes In Vivo" teaches in column 4 lines 20-23, diboronic acids for detecting glucose. Fluorescent compounds are taught in column 5. Various matrices are shown in columns 5-6 as well. In column 6 lines 27-34, the sensor may be implanted in the skin.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by DiCesare.

DiCesare (Anal Biochem) entitled "Evaluation of Two Synthetic Glucose Probes for Fluorescence Lifetime Based Sensing" teaches on page 155 Fig. 1, two boronic acid compounds for detecting glucose.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinkai.

Shinkai (Trends in Analytical Chemistry) entitled "Molecular Design of Artificial Sugar Sensing Systems" teaches on page 189 structure s 6 and 7 for detecting glucose.

All the features of the claims are taught by the above references for the same function as claimed.

Applicant's arguments filed 1/27/04 have been fully considered but they are not persuasive.

Applicants argue that the above cited references do not state that the interaction between the compound and glucose is more stable than the interaction between the compound and an alpha hydroxy acid or beta diketone and that the presence of the alpha hydroxy acid or beta diketone does not substantially interfere with the determination of glucose. Further, the Friedman reference teaches that phenylboronic acid forms stable complexes with lactic acid so one would not expect any diboronic acid to detect glucose without interference from lactic acid.

It is the examiner's position that the present claims are method claims for determining glucose with specific compounds and the references teach determining glucose with the same compounds. That the determination would then not have certain

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interferences is inherent in the method because the same compounds are reacted for the same function.

Regarding Friedman, the presently claimed compounds are different compounds from those taught by Friedman who teaches phenylboronic acids.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Primary Examiner  
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